Master of Science Program

«Research Methodology in Biomedicine, Biostatistics and Clinical Bioinformatics»

School of Medicine | School of Health Sciences | University of Thessaly

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Master of Science's Thesis

«Assess the reporting quality of meta-analyses of randomized controlled trials (RCTs) in otitis media with effusion, published from 1991 to date, based on PRISMA statement.»

«Αξιολόγηση της ποιότητας των μετα-αναλύσεων των τυχαιοποιημένων ελεγχόμενων δοκιμών για την εκκριτική μέση ωτίτιδα, που έχουν εκδοθεί από το 1991 έως και σήμερα, με βάση το PRISMA Statement.»

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Abstract

Introduction Insufficient assessment of reporting quality of meta-analyses of RCTs on otitis media with effusion (OME), is associated with biased conclusions concerning its prevention and treatment.

Objectives The aim of this study is to assess the quality of meta-analyses of RCTs on OME that have been published from 1991, using an eligible tool based on Preferred Reporting Items of Systematic reviews and Meta-Analyses (PRISMA) Statement.

Methods Pubmed database search for meta-analyses of RCTs on OME, in English language, published from 1991 to 2017. Their reporting quality was assessed using a 27-item questionnaire based on PRISMA Statement. Adherence to PRISMA was tested between pre- and post-PRISMA period in overall and regarding conservative and surgical treatment of OME.

Results 21 eligible meta-analyses were included, with 22 out of 27 items of PRISMA checklist being reported in more than 50% of them. There is statistically no significant diffenerce in the reporting quality between the two periods, in overall and regarding further comparisons. Only two journals on otorhinolaryngology have endorsed PRISMA statement.

Conclusion Reporting quality of meta-analyses of RCTs on OME varies. PRISMA Statement is an essential tool to ensure the quality of reporting and decision making in the clinical practice and should be endorsed by more scientific journals.

Abbreviations: RCTs – Randomized controlled trials, OME – otitis media with effusion, PRISMA - Preferred Reporting Items of Systematic reviews and Meta-Analyses

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Περίληψη

Εισαγωγή Η ανεπαρκής αξιολόγηση της ποιότητας των μετα-αναλύσεων τυχαιοποιημένων ελεγχόμενων δοκιμών (ΤΕΔ), με θέμα την εκκριτική μέση ωτίτιδα (ΕΜΩ), σχετίζεται με επισφαλή συμπεράσματα αναφορικά με την πρόληψη και αντιμετώπισή της.

Στόχοι Σκοπός της εργασίας είναι η αξιολόγηση της ποιότητας των μετα-αναλύσεων των ΤΕΔ με θέμα την ΕΜΩ, που έχουν εκδοθεί από το 1991, χρησιμοποιώντας ένα δομημένο εργαλείο με βάση το PRISMA Statement.

Μέθοδοι Αναζήτηση στη βάση δεδομένων Pubmed, μετα-αναλύσεων ΤΕΔ, που αφορούν στην ΕΜΩ, στην αγγλική γλώσσα και έχουν εκδοθεί από το 1991 έως το 2017. Η ποιότητα τους αξιολογήθηκε με ένα ερωτηματολόγιο 27 στοιχείων, βάσει του PRISMA Statement και η πίστη τους σε αυτό αξιολογήθηκε πριν και μετά την έκδοση του, συνολικά και αναφορικά με τη συντηρητική και χειρουργική αντιμετώπιση της.

Αποτελέσματα 21 σχετικές μετα-αναλύσεις αξιολογήθηκαν, με 22 από τα 27 στοιχεία του PRISMA να αναφέρονται σε περισσότερες από το 50% αυτών. Δεν παρατηρείται στατιστικά σημαντική διαφορά πριν και μετά την έκδοση του, συνολικά και στις επιμέρους συγκρίσεις. Δύο περιοδικά ωτορινολαρυγγολογίας έχουν υιοθετήσει το PRISMA statement.

Συμπέρασμα Η ποιότητα των μετα-αναλύσεων των ΤΕΔ για την ΕΜΩ ποικίλει. Η χρήση του PRISMA Statement αποτελεί σημαντικό εργαλείο για τη διασφάλιση της ποιότητας και της εξαγωγής ασφαλών συμπερασμάτων, για αυτό συστήνεται η υιοθέτησή του από περισσότερα επιστημονικά περιοδικά.

Συντομογραφίες: ΤΕΔ – τυχαιοποιημένες ελεγχόμενες δοκιμές ή τυχαιοποιημένες ελεγχόμενες κλινικές μελέτες, ΕΜΩ – Εκκριτική μέση ωτίτιδα

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Introduction

Meta-analysis is an essential tool for outlining evidence in an accurate and reliable way. It helps clinical doctors and researchers to keep up-to-date; informs about the risks and benefits of interventions to different types of patients, about patient behaviors and reactions; provides crucial evidence to decision-making for the clinical practice; presents summaries of conducted research and reviews, giving information, inspiration and ideas for future research goals. [1]

To serve these objectives, not only the conduction, but also the reporting quality of meta-analyses should be optimal. Evidence that reporting quality of systematic reviews and meta-analyses is suboptimal [2], led to the development of an assessment tool by a team of authors, reviewers, methodologists and researchers, in order to assess and enhance the reporting quality of these studies in the long run. That tool was QUORUM (Quality of Reporting of Meta-analyses) Statement and it was published in 1999. [1] In 2009, in terms of improving this existing reporting quality assessment system, PRISMA (Preferred Reporting Items of Systematic reviews and Meta-Analyses) Statement was published. The goal of this statement was to achieve a more transparent and structured way of reporting evidence of systematic reviews and meta-analyses. [1] Internet presence of this statement can be accessed in this link http://www.prisma-statement.org.

Otitis media with effusion (OME) is one of the most common diseases in children and the most common cause of hearing loss in early childhood. [3, 4] It is defined as presence of middle ear fluid in the absence of infection. [5] Meta-analyses have been conducted upon its prevention, treatment and complications of treatment. These analyses regarding OME, focus especially on treatment of it, either conservative with the use of antibiotics, steroids and vaccination or surgical treatment, including tumpanostomy tube placement and adenoidectomy. Tympanostomy tube placement is the main surgical treatment of OME in children, being the second most common pediatric surgery in the United States. [6, 7]

A research article by Peters JPM et al. published in 2015, testing the adherence to PRISMA Statement for Abstracts in Ear, Nose and Throat (ENT) journals and in Cochrane Database for Systematic Reviews (CDSR), revealed that ENT journals reported a median of 54,4% of PRISMA items, whereas CDSR a total of 100% of PRISMA items and concludes that there is a need for improvement in the reporting quality of such articles in ENT journals. [2]

The aim of this study was to assess the methodological quality of these meta-analyses in an attempt to identify the level of significance in the results of them and the power of influence in future decision-making in clinical practice. So far, there has been no published study assessing the reporting quality of meta-analyses of RCTs in OME to our knowledge, during this time-period of 26 years, whereas there have been studies assessing the reporting quality of

both Systematic Reviews and Meta-analyses in ENT-related topics in general, referring to a short time-period. [2]

Our objectives were to conduct an assessment of reporting quality of meta-analyses of RCTs on OME, published from 1991 to June 2017, using a 27-item tool based on PRISMA Statement and to determine whether this reporting quality has improved since 2009, when PRISMA Statement was introduced. Morever, adherence to PRISMA statement of meta-analyses on conservative treatment and on surgical treatment of OME between these two periods will be tested separately.

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Methods

Study selection

A systematic literature research was performed on Pubmed database for meta-analyses of RCTs on OME, using the filter *meta-analysis* and keywords *otitis media with effusion, secretory otitis media, glue ear* and *tympanostomy tube*, separately, published from 1991 to June 2017. The selection of this date, included every possible meta-analysis that has been conducted on this topic and has been published online on Pubmed. Moreover, we conducted a search using no filter with keywords *otitis media with effusion AND meta-analysis*, *tympanostomy tube placement AND meta-analysis* producing similar results.

The study eligibility criteria included only meta-analyses that referred to RCTs, were written in English language, published from 1991 to June 2017, focusing on OME and its treatment methods. Only meta-analyses for which full-text articles could be obtained were included in this study. Language restrictions limited the number of included references to those written in English language. Further reasons for study exclusion are identified in **Table 2**.

The articles were reviewed independently by the author and their reporting quality was assessed using a 27-item questionnaire based on PRISMA Statement, published in 2009. The reporting of each item was assessed individually, by a definite answer (yes or no), whereas any alternative response was considered as a negative one. For item (20), items (20-a) and (20-b) were reported individually and if the reporting of one of them was considered as negative, item 20 was also considered as negative in total.

Statistical Methods

Two publication periods were formed, the first from 1991 to 2008 (pre-PRISMA period) and the second from 2009 to 2017 June (post-PRISMA period). Adherence to PRISMA Statement between the two publication periods was compared by calculating the respective Odds Ratio (OR) and 95% Confidence Interval (95% CI) of reporting an item in the pre- or post-PRISMA Statement period. Comparisons between the two periods were tested by using the Fisher's exact test. The statistical package used for this data analysis was SPSS 24. Statistical significance was set to 0.05.

In advance, comparisons were tested between pre- and post-PRISMA period regarding two different groups of studies, one concerning conservative treatment of OME (n=8) and the other concerning surgical treatment of OME (n=11), by calculating the respective OR and 95% CI, with 0.05 level of significance, as mentioned above.

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Table 1. Reporting of 27 items in 21 meta-analyses in otitis media with effusion for the time period 1991-2017 (in total and pre- and post-PRISMA period respectively).

Data items	Total[#] (n=21)	Pre-PRISMA (1991-2008) (n=12)	Post-PRISMA (2009-2017) (n=9)	OR and 95% CI^	P-value
Title					
1. Identify as a Sys Rev or/and meta-analysis	0.67 (14)	0.66 (8)	0.67 (6)	1 [0.160, 6.255]	1
Abstract					
2. Structured Summary	0.90 (19)	0.83 (10)	1 (9)	NA*	0.486
Introduction					
3. Rationale	1 (21)	1 (12)	1 (9)	NA	NA
4. Objectives	0.86 (18)	0.75 (9)	1 (9)	NA	0.229
Methods					
5. Protocol/Registration No	0.38 (8)	0.33 (4)	0.44 (4)	1.6 [0.270, 9.490]	0.673
6.Eligibility criteria/Study characteristics	0.90 (19)	1 (12)	0.78 (7)	NA	0.171
7. Information sources	0.90 (19)	0.83 (10)	1 (9)	NA	0.486
8. Search	0.71 (15)	0.75 (9)	0.67 (6)	0.667 [0.099, 4.478]	1
9. Study selection	0.71 (15)	0.67 (8)	0.78 (7)	1.75 [0.242, 12.642]	0.659
10. Data collection process	0.81 (17)	0.75 (9)	0.89 (8)	2.667 [0.229, 31.069]	0.603
11. Data items	0.62 (13)	0.75 (9)	0.44 (4)	0.267 [0.042, 1.702]	0.203
12. Risk of bias in individual studies	0.43 (9)	0.25 (3)	0.67 (6)	6 [0.893, 40.306]	0.087
13. Summary measures	0.67 (14)	0.75 (9)	0.56 (5)	0.417 [0.065, 2.66]	0.397
14. Synthesis of results	0.95 (20)	1 (12)	0.89 (8)	NA	0.429
15. Risk of bias across studies	0.43 (9)	0.5 (6)	0.33 (3)	0.5 [0.084, 2.992]	0.660
16. Additional analyses	0.52 (11)	0.67 (8)	0.33 (3)	0.250 [0.040, 1.564]	0.198
Results					
17. Study selection	0.71 (15)	0.58 (7)	0.89 (8)	5.714 [0.532, 61.410]	0.178
18. Study characteristics	0.76 (16)	0.83 (10)	0.67 (6)	0.4 [0.051, 3.125]	0.611
19. Risk of bias within studies	0.33 (7)	0.17 (2)	0.56 (5)	6.25 [0.839, 46.57]	0.159
20. Results of individual studies	0.81 (17)	0.83 (10)	0.78 (7)	0.7 [0.079, 6.224]	1
21. Synthesis of results	0.95 (20)	0.92 (11)	1 (9)	NA	1
22. Risk of bias across studies	0.24 (5)	0.17 (2)	0.33 (3)	2.5 [0.32, 19.529]	0.611
23. Additional analysis	0.62 (13)	0.58 (7)	0.67 (6)	1.429 [0.236, 8.637]	1
Discussion					
24. Summary of evidence	1 (21)	1 (12)	1 (9)	NA	NA
25. Limitations	1 (21)	1 (12)	1 (9)	NA	NA
26. Conclusions	1 (21)	1 (12)	1 (9)	NA	NA
Funding					
27. Funding	0.57 (12)	0.42 (5)	0.78 (7)	4.9 [0.7, 34.3]	0.184

Percentage of references reporting the PRISMA item in the respective time period
^ Odds ratio of reporting an item in post-PRISMA period compared to reporting in pre-PRISMA period
*NA = not applicable

Results

Search in Pubmed database revealed 52 studies, of which only 21 meta-analyses were eligible to be included in this analysis. Two groups of these studies were formed based on the publication year: 12 of them were published before 2009 and 9 of them after 2009, the year that PRISMA Statement was published. The flow diagram of articles screened and retrieved during the search strategy, is presented in **Figure 1**.

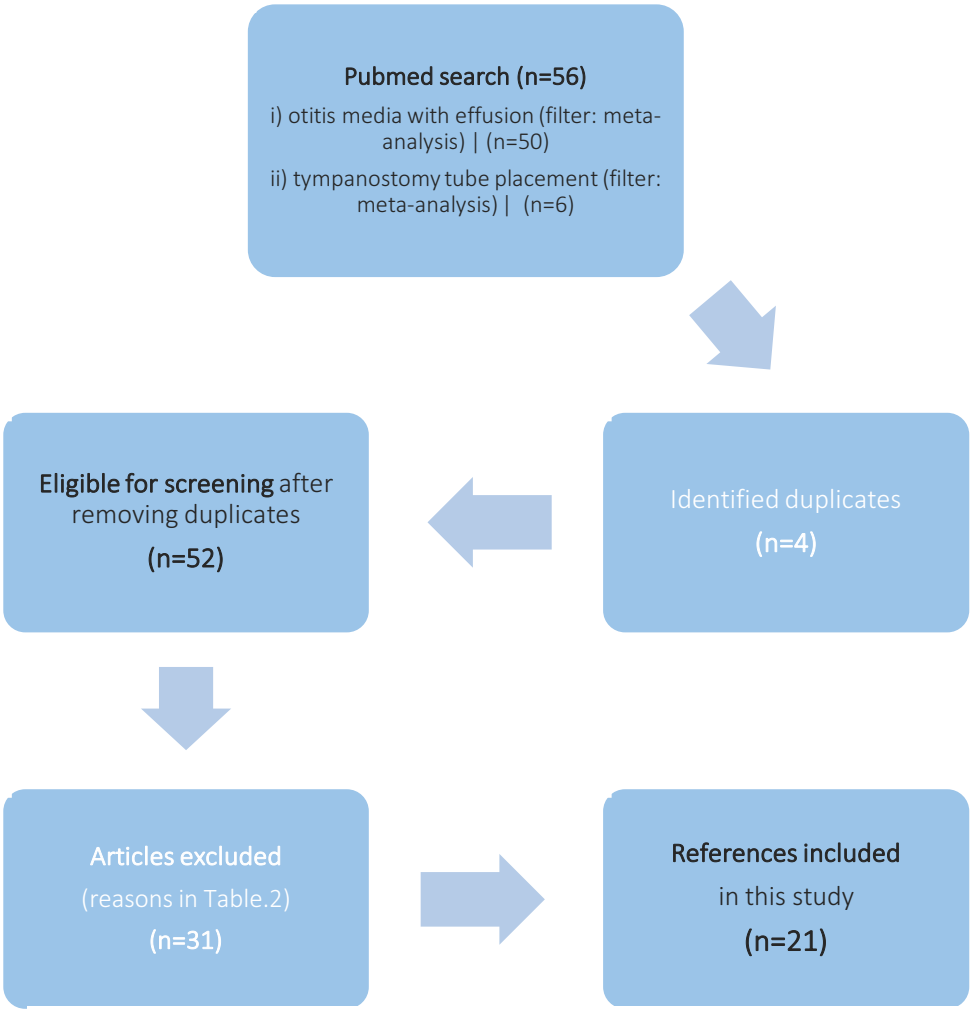

Figure 1. Flow diagram of references retrieved and screened during the search strategy.

When these 21 meta-analyses are taken into consideration together, 22 out of the 27 items are being reported in more than 50% of the studies with a range from 52-100%, whereas 5 items including risk of bias and review protocol are reported in less than 50% of the studies. 4 items are being reported in 100% of the articles, them being *(3) Rationale (Introduction)* and

(24) Summary of evidence, (25) Limitations, (26) Conclusions (Discussion). The lowest score is identified in items regarding risk of bias within studies and across studies in the results, being reported in 33% and 24% of the meta-analyses, respectively, in overall.

Table 2. Study exclusion criteria

Reason for exclusion of study	Number of articles excluded
Other language (except for English)	n=1
Meta-analysis does not include RCTs	n=2
Not available full text of meta-analysis	n=2
Other types of study on OME (not meta-analysis)	n=19
Not relevant to topic	n=7
Total number of references excluded	**n=31**

After comparing the two periods of publication, before 2009 and after 2009, no statistically significant improvement was identified in any of the 27 items reported, though P-value (0.087) for item *(12) Risk of individual studies (Methods)* is close to statistical significance, set to 0.05 level. Reporting of 14 items revealed improvement after publication of PRISMA Statement in 2009, with biggest improvement of 42% in reporting of *(12) Risk of individual studies (Methods)*, 39% in *(19) Risk of bias within studies (Results*), 36% in *(27) Funding* and 31% in *(17) Study selection*. On the other hand, there has been a decrease in reporting of 13 items, the biggest being 34% decrease in *(16) Additional analyses (Methods)* and 31% in *(11) Data items definition (Methods)*.

19 of these studies were grouped based on the type of treatment they introduce and test. 2 studies were excluded from this further analysis, because one of them focuses on the effect of OME on language and behavioral development of the child and the other on natural healing process of OME. One group of studies (n=8) focuses on the conservative treatment of OME, including antibiotics, steroids and vaccination for the prevention of OME, whereas the second group (n=11) is focused on the surgical treatment of OME, including tympanostomy tube placement, adenoidectomy and their sequelae. In **Table 3** and **Table 4**, there is a summary of the results of reporting quality of each group of studies before and after publication of PRISMA statement.

Regarding the conservative treatment of OME, 5 articles were published before PRISMA and 3 articles after its publication. Results are presented in **Table 3**. No statistically significant difference is identified between the reporting quality of the two periods. 14 out of 27 items' reporting quality improved in the post-PRISMA period, the same as in overall comparison in **Table 2**. 25 out of the 27 items are being reported in more than 50% of the studies. The highest improvement score was in item *(8) Search (Methods)* of 40%.

Table 3. Reporting of 27 items in 8 meta-analyses in conservative treatment of OME for the time period 1991-2017 (in total and pre- and post-PRISMA period respectively).

Data items	Total[#] (n=8)	Pre-PRISMA (1991-2008) (n=5)	Post-PRISMA (2009-2017) (n=3)	OR and 95% CI^	P-value
Title					
1. Identify as a Sys Rev or/and meta-analysis	0.625 (5)	0.60 (3)	0.67 (2)	1.333 [0.067, 26,618]	1
Abstract					
2. Structured Summary	0.88 (7)	0.80 (4)	1 (3)	NA*	1
Introduction					
3. Rationale	1 (8)	1 (5)	1 (3)	NA	NA
4. Objectives	0.88 (7)	0.80 (4)	1 (3)	NA	1
Methods					
5. Protocol/Registration No	0.25 (2)	0.40 (2)	0 (0)	NA	0.464
6.Eligibility criteria/Study characteristics	0.88 (7)	1 (5)	0.67 (2)	NA	0.375
7. Information sources	0.88 (7)	0.80 (4)	1 (3)	NA	1
8. Search	0.75 (6)	0.60 (3)	1 (3)	NA	0.464
9. Study selection	0.63 (5)	0.60 (3)	0.67 (2)	1.333 [0.067, 26.618]	1
10. Data collection process	0.88 (7)	0.80 (4)	1 (3)	NA	1
11. Data items	0.75 (6)	0.80 (4)	0.67 (2)	0.5 [0.019, 12.898]	1
12. Risk of bias in individual studies	0.63 (5)	0.60 (3)	0.67 (2)	1.333 [0.067, 26.618]	1
13. Summary measures	0.88 (7)	1 (5)	0.67 (2)	NA	0.375
14. Synthesis of results	0.88 (7)	1 (5)	0.67 (2)	NA	0.375
15. Risk of bias across studies	0.75 (6)	0.80 (4)	0.67 (2)	0.5 [0.019, 12.898]	1
16. Additional analyses	0.63 (5)	0.60 (3)	0.67 (2)	1.333 [0.067, 26.618]	1
Results					
17. Study selection	0.88 (7)	0.80 (4)	1 (3)	NA	1
18. Study characteristics	1 (8)	1 (5)	1 (3)	NA	NA
19. Risk of bias within studies	0.5 (4)	0.40 (2)	0.67 (2)	3 [0.150, 59.890]	1
20. Results of individual studies	1 (8)	1 (5)	1 (3)	NA	NA
21. Synthesis of results	1 (8)	1 (5)	1 (3)	NA	NA
22. Risk of bias across studies	0.25 (2)	0.20 (1)	0.33 (1)	2 [0.078, 51.593]	1
23. Additional analysis	0.88 (7)	0.80 (4)	1 (3)	NA	1
Discussion					
24. Summary of evidence	1 (8)	1 (5)	1 (3)	NA	NA
25. Limitations	1 (8)	1 (5)	1 (3)	NA	NA
26. Conclusions	1 (8)	1 (5)	1 (3)	NA	NA
Funding					
27. Funding	0.63 (5)	0.60 (3)	0.67 (2)	1.333 [0.067, 26.618]	1

Percentage of references reporting the PRISMA item in the respective time period
^ Odds ration of reporting an item in post-PRISMA period compared to reporting in pre-PRISMA period
*NA = not applicable

On the other hand, comparison between the two publication periods regarding the surgical treatment of OME, reveal 5 articles published in the pre-PRISMA period and 6 articles in the post-PRISMA period, presenting more promising results. Improvement in reporting quality of item *(12) Risk of individual studies (Methods)* and *(27) Funding (12)* is close to statistical significance, with a P-value 0.061 and 0.080 respectively. 13 out of 27 items' reporting quality improved in the post-PRISMA period, the greatest difference calculated in items (12) and (27), as mentioned above, with a magnitude of 67% and 63% respectively. In this case, 19 out of 27 items are reported in total in more than 50% of the studies.

Table 4. Reporting of 27 items in 11 meta-analyses in surgical treatment of OME for the time period 1991-2017 (in total and pre- and post-PRISMA period respectively).

Data items	Total[#] (n=11)	Pre-PRISMA (1991-2008) (n=5)	Post-PRISMA (2009-2017) (n=6)	OR and 95% CI^	P-value
Title					
1. Identify as a Sys Rev or/and meta-analysis	0.73 (8)	0.80 (4)	0.67 (4)	0.5 [0.031, 7.994]	1
Abstract					
2. Structured Summary	0.91 (10)	0.80 (4)	1 (6)	NA*	0.455
Introduction					
3. Rationale	1 (11)	1 (5)	1 (6)	NA	NA
4. Objectives	0.82 (9)	0.60 (3)	1 (6)	NA	0.182
Methods					
5. Protocol/Registration No	0.45 (5)	0.20 (1)	0.67 (4)	8 [0.500, 127.900]	0.242
6.Eligibility criteria/Study characteristics	0.91 (10)	1 (5)	0.83 (5)	NA	1
7. Information sources	0.91 (10)	0.80 (4)	1 (6)	NA	0.455
8. Search	0.64 (7)	0.80 (4)	0.50 (3)	0.250 [0.017, 3.770]	0.545
9. Study selection	0.73 (8)	0.60 (3)	0.83 (5)	3.333 [0.204, 54.532]	0.545
10. Data collection process	0.73 (8)	0.60 (3)	0.83 (5)	3.333 [0.204, 54.532]	0.545
11. Data items	0.45 (5)	0.60 (3)	0.33 (2)	0.333 [0.028, 3.926]	0.567
12. Risk of bias in individual studies	0.36 (4)	0 (0)	0.67 (4)	NA	0.061
13. Summary measures	0.55 (6)	0.60 (3)	0.50 (3)	0.417 [0.065, 2.66]	1
14. Synthesis of results	1 (11)	1 (5)	1 (6)	NA	NA
15. Risk of bias across studies	0.18 (2)	0.20 (1)	0.17 (1)	0.8 [0.037, 17.196]	1
16. Additional analyses	0.36 (4)	0.60 (3)	0.17 (1)	0.133 [0.008, 2.181]	0.242
Results					
17. Study selection	0.64 (7)	0.4 (2)	0.83 (5)	7.5 [0.458, 122.696]	0.242
18. Study characteristics	0.55 (6)	0.60 (3)	0.50 (3)	0.667 [0.060, 7.352]	1
19. Risk of bias within studies	0.27 (3)	0 (0)	0.50 (3)	NA	0.182
20. Results of individual studies	0.64 (7)	0.60 (3)	0.67 (4)	1.333 [0.113, 15.704]	1
21. Synthesis of results	0.91 (10)	0.80 (4)	1 (6)	NA	0.455
22. Risk of bias across studies	0.27 (3)	0.20 (1)	0.33 (2)	2.5 [0.32, 19.529]	1

23. Additional analysis	0.36 (4)	0.20 (1)	0.50 (3)	4 [0.265, 60.325]	0.545
Discussion					
24. Summary of evidence	1 (11)	1 (5)	1 (6)	NA	NA
25. Limitations	1 (11)	1 (5)	1 (6)	NA	NA
26. Conclusions	1 (11)	1 (5)	1 (6)	NA	NA
Funding					
27. Funding	0.55 (6)	0.20 (1)	0.83 (5)	20 [0.930, 429.904]	0.080

Percentage of references reporting the PRISMA item in the respective time period
^ Odds ration of reporting an item in post-PRISMA period compared to reporting in pre-PRISMA period
*NA = not applicable

In **Table 5**, the journals where these 21 studies are published, are presented. After searching in the PRISMA Datatabase of Endorsers (found in this link: http://www.prisma-statement.org/Endorsement/PRISMAEndorsers), only 2 out of these 9 journals, them being *Pediatrics* and *JAMA* have already endorsed PRISMA Statement, representing 19% of the articles. The rest 81% of the articles has been published in non-endorser journals, according to the database above. Interesting is the fact that none of these journals that focuses on Otorhinolaryngology itself, has endorsed PRISMA Statement. Searching the above mentioned database, only 2 Otorhinolaryngology journals are identified as endorsers of PRISMA Statement, *BMC Ear Nose and Throat Disorders* and *Head and Neck Oncology*.

Table 5. Endorsement of PRISMA Statement by journals included in this study

	Journals (n=9)	Articles published (n=21)*	Endorsement of PRISMA Statement
1	Archives of Otolaryngology Head and Neck Surgery	28.6% (n=6)	no
2	Pediatrics	14.2 % (n=3)	yes
3	International Journal of Pediatric Otorhinolaryngology	14.2 % (n=3)	no
4	Vaccine	9.5% (n=2)	no
5	European Archives of Oto-Rhino-Laryngology	9.5% (n=2)	no
6	The Laryngoscope	9.5% (n=2)	no
7	JAMA	4.8% (n=1)	yes
8	Archives of Disease in Childhood	4.8% (n=1)	no
9	Health Technology Assessment	4.8% (n=1)	no

*Percentage of articles included in this study that are published in the respective journal

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Discussion

This study presents evidence that the reporting quality of meta-analyses of RCTs on OME, according to a 27-item questionnaire based on the PRISMA Statement, is low. No statistically significant difference is identified in the reporting quality before and after the publication of PRISMA Statement in overall. PRISMA items that are more general, such as *(3) Rationale (Introduction)* and *(24) Summary of evidence, (25) Limitations, (26) Conclusions (Discussion)* appear to be referred in most of the articles, whereas items that require significant methodological quality, such as *(12) Risk of individual studies (Methods)* and *(19) Risk of bias within studies (Results*), have a lower reporting score, introducing possible bias in the decision-making on clinical practice.

Further comparisons of the reporting quality of meta-analyses focusing on conservative treatment and on surgical treatment of OME, in the pre- and post-PRISMA period, reveal similar results, with a better adherence to PRISMA Statement for surgical treatment of OME. Differences in the reporting quality of studies on surgical compared to conservative treatment, present results closer to statistical significance for items (27) Funding and (12) Risk of individual studies, that seem to have adhered better to PRISMA checklist. Surgical treatment of OME by tympanostomy tube placement being one of the most common pediatric surgeries [6, 7], seems to draw more research attention, which may expain the reporting of funding and risk of bias and in general, in a greater extend.

A possible explanation for the low score in the assessment of reporting quality of these articles in total, might be that only 2 out of the 7 journals included in this study have endorsed PRISMA Statement so far. None of the three ENT journals taken into consideration in this study has endorsed PRISMA Statement. In the PRISMA-endorsers database, only two ENT journals are identified, BMC Ear Nose and Throat Disorders and Head and Neck Oncology. Further endorsement of PRISMA Statement by these journals is recommended in order to enhance the reporting quality of meta-analyses of RCTs on otorhinolaryngologic topics, such as otitis media with effusion.

Regarding the selection bias, concerning language, there was only one analysis that was not included in this study, that was written in Chinese lanaguage, making the possibility of this type of bias low.

Finally, the number of studies involved in this analysis is limited, especially regarding to further subgrouping analysis, which may lead to biased conclusions regarding statistical significance of the results. The number, though, represents all the available eligible studies in Pubmed database on OME. Further research needs to be conducted in the future, concerning the reporting quality of this and other ENT topics and the adherence of ENT journals to PRISMA statement both on Systematic Reviews and on Meta-Analyses.

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Conclusion

To conclude with, there is evidence that the reporting quality of meta-analyses of RCTs on OME remains low, despite the publication of PRISMA Statement in 2009. More otorhinolaryngologic journals should endorse PRISMA Statement, in order to enhance the reporting quality of articles and to ensure the safety in the decision-making for the clinical practice and patient care, for diseases such as OME that affect a lot of children and have a great impact in their quality of life.

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